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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/510,937 02/22/00 CAMPBELL

C MP/55G

EXAMINER

HM22/0102

WAYNE D. HOUSE
W.L. GORE & ASSOCIATES, INC.
551 PAPER MILL ROAD
P.O. BOX 9206
NEWARK DE 19714-9206

MOHAMED, A

ART UNIT

PAPER NUMBER

1653

5

DATE MAILED:

01/02/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/510,937

Applicant(s)

CAMPBELL ET AL

Examiner

MOHAMED

Group Art Unit

1653

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 10/18/00 and 11/21/00
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-9 is/are pending in the application.
- ☐ Of the above claim(s) is/are withdrawn from consideration.
- ☐ Claim(s) is/are allowed.
- ☒ Claim(s) 1-9 is/are rejected.
- ☐ Claim(s) is/are objected to.
- ☐ Claim(s) are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____
 - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 4(4 pages)
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

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DETAILED ACTION

ACKNOWLEDGMENT OF AMENDMENT, REMARKS, TERMINAL DISCLAIMER, IDS AND STATUS OF THE CLAIMS

1. The amendment, remarks and terminal disclaimer (TD) filed 10/18/00 and the information disclosure statement (IDS) and Form PTO-1449 filed 11/21/00 are acknowledged, entered and considered. With respect to the IDS, copies of some of the references cited therewith on Form PTO-1449 are not provided in the instant specification. However, as *per* Applicant's request, since the cited references were considered previously in the parent applications Serial Nos. 08/247,960, 08/108,963 and 08/204,708; pursuant to 37 CFR § 1.98(d), the references cited in Form PTO-1449 in this application have been considered and signed as requested by Applicant. In view of Applicant's request claim 1 has been amended. Thus, claims 1-9 are now pending in the application. The rejections under the judicially created doctrine of double patenting, 35 U.S.C. 102(b) and 35 U.S.C. 103(a) over the prior art of record are maintained.

HEADING FOR NONSTATUTORY DOUBLE PATENTING

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed.

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Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

DOUBLE PATENTING, NON-STATUTORY WITH PATENTS

3. Claims 1-9 remain rejected under the judicially created doctrine of double patenting over claims 1-22, 1-40 and 1-2, respectively of U. S. Patent Nos. 6,027,779, 6,025,044 and 6,027,811, respectively since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patents.

The subject matter claimed in the instant application is fully disclosed in the patents and is covered by the patents since the patents and the application are claiming common subject matter, as follows: The instantly claimed invention and the patents teach a PTFE tube with specific architecture and structure in which a thin-wall may be used in a non-porous embodiment as the balloon portion of a balloon catheter (See e.g., col. 9, lines 7-16; col. lines 57 to col. 10, lines 5; Figures 16A and 16B and 20 of U.S. Patent No. 6,027,779)..

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CLAIMS REJECTION-35 U.S.C. § 102(b)

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 and 8-9 remain rejected under 35 U.S.C. 102(b) as being anticipated by Buck et al. (U.S. Patent No. 4,925,710).

The independent claim 1 is drawn to a non-porous catheter balloon comprising porous polytetrafluoroethylene (PTFE) and a non-porous coating. The dependent claims 2-3 and 8-9 are drawn to particularly to non-porous coating comprising fluorinated ethylene propylene (claim 2), multiple layers of porous PTFE (claim 8), continuous coating (claim 9), and an adhesive (claim 3), wherein the adhesive comprises a thermoplastic adhesive (claim 4), and wherein the thermoplastic adhesive is a thermoplastic fluoropolymer (claim 5).

Buck et al. disclose a thin-wall non-porous tube comprising porous PTFE and a non-porous coating comprising polymers such as fluorinated ethylene propylene and commercially available thermoplastic adhesives such as thermoplastic fluoropolymers (See e.g., col. 2, lines 49 to col 3, lines 46). Although, on column 7, lines 10 to 13, the reference states that the nature or number of the layers in the outer sheath of the multilayered tube is not critical and can be selected

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as desired for the particular application contemplated. Nevertheless, the reference clearly discloses the use of non-porous coating comprising multiple layers of porous PTFE as well as the employment of a continuous coating (See e.g. abstract, Example , claims 1 and 16).

The reference does not disclose the intended use of the PTFE tube as “a catheter balloon” Nevertheless, a statement of usefulness or contemplated use of a claimed compound or composition in a claim is usually given little weight in distinguishing over the prior art. In re Maeder et al. (CCPA 1964) 337 F2d 875, 143 USPQ 248; In re Riden et al. (CCPA 1963) 318 F2d 761, 138 USPQ 112; In re Sinex (CCPA 1962) 309 F2d 488, 135 USPQ 302. Thus, in the absence of evidence to the contrary or specific structural limitations, the claimed PTFE tube disclosed by the reference anticipates claims 1-5 and 8-9 as drafted.

CLAIMS REJECTION-35 U.S.C. 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) a patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to

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the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(a) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-9 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Buck et al. (U.S. Patent No. 4,925,710) in view of Gore (U.S. Patent No. 3,953,566) and Soltesz (U.S. Patent No. 5,254,107).

The patent of Buck et al. has been discussed under the rejections of 102(b) above with respect to the disclosure of a thin-wall non-porous tube comprising porous PTFE and a non-porous coating comprising polymers such as fluorinated ethylene propylene and commercially available thermoplastic adhesives such as thermoplastic fluoropolymers and the use of non-porous coating comprising multiple layers of porous PTFE as well as the employment of a continuous coating.

The patent of Buck et al. differs particularly from claims 6-7 in failing to teach the use of a porous PTFE tube comprising a porous expanded PTFE and wherein the balloon is an inelastic balloon. However, the reference of Gore 566' teaches the process for producing porous products of all kinds of shaped articles such as tubes and sheet films of porous expanded PTFE, wherein the PTFE has a microstructure of nodes interconnected by fibrils (See the entire document and particularly the abstract and claims). Further, the patent of Soltesz 107' the construction of

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catheter tube having a middle layer of wire reinforcement which is enclosed by inner and outer layers which are described as being tubular thermoplastic sections. Thus, the resulting catheter corresponding to the first and second catheter sections exhibits different properties in a manner corresponding to the different properties of thermoplastic materials used (See e.g., col. 3, lines 3-16). Further, on col. 3, lines 40 to 43, the reference clearly states that the inner tubular plastic layer may be made of PTFE or the like. Hence, clearly showing the use of PTFE and thermoplastic material in the construction of catheter tube.

With respect to the structure of the balloon to be an inelastic balloon, although, the prior art does not teach the use or construction of balloon *per se*, however, the prior art clearly teach the use or construction of thin-wall tube comprising porous PTFE and a non-porous coating, and as such, it would be conventional and within the ordinary skill in the art to which this invention pertains to expect the tube to be inelastic because the prior art used the same material/composition under substantially the same situation to make the thin-wall catheter tube as the instant claimed thin-wall catheter balloon. Therefore, in the absence of sufficient objective factual evidence or unexpected results to the contrary, it would have been obvious to expect the tube of the prior art to be inelastic tube because of the reasonable expectation of the functional equivalency of the non-porous coating material.

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ARGUMENTS ARE NOT PERSUASIVE

6. The rejection of claims 1-9 under the judicially created doctrine of double patenting over claims 1-22, 1-40 and 1-2, respectively of U. S. Patent Nos. 6,027,779, 6,025,044 and 6,027,811, respectively since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patents for the same reasons discussed in the previous Office action. Although, Applicant has filed a terminal disclaimer (TD), however, the TD is not proper and has not been accepted because the serial number of the application (or the number of the patent) which forms the basis for double patenting is missing or incorrect (See 14.32). In the instant case, there is no double patenting rejection with grand parent application Serial No. 08/108,963 because this application has not been patented, but disclaimed by the owner, W. L. Gore & Associates. Inc., while there is no disclaimer for double patenting rejection on Serial No. 08/486,124, now U.S. Patent No. 6,027,811. It is believed to be typographical error. Therefore, it is suggested that Applicant file a proper TD with correct application number (i.e., Serial No. 08/486,963 instead of Serial No. 08/108,963) corresponding to correct patent number in order to overcome the judicially created doctrine of double patenting.

7. The rejection of claims 1-5 and 8-9 under 35 U.S.C. 102(b) as being anticipated by Buck et al. (U.S. Patent No. 4,925,710).

Applicant asserts that the tube of Buck et al. is not comprised of porous PTFE because there is no evidence of this in the entire specification. Contrary to Applicant's assertion, the '710

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patent of Bucks et al. on col. 2, lines 49 to col. 3, lines 46 discloses a thin-wall non-porous tube comprising porous PTFE and a non-porous coating comprising polymers such as fluorinated ethylene propylene and commercially available thermoplastic adhesives such as thermoplastic fluoropolymers.

With respect to Applicant's recitation that the PTFE of Buck et al. is described as optionally containing fillers such as spherical glass beads as stated on col. 4, lines 48-57 and there is absolutely no indication that the resulting tube is porous through its wall, and as such, the '710 patent of Buck et al. teaches away from the use fillers that are volatile or leachable which might be used to achieve a truly porous tube is noted. However, this is irrelevant because the '710 patent on col. 4, lines 30-32 states that the filler material may come in particles of any shape including spheres, rods, fibers, random angular shapes, etc., Thus, clearly showing that other fillers in various and/or any shape can be used, although, the preferred one is spherical.

In regard to Applicant's arguments that the '710 patent of Buck et al. does not teach or suggest in any fashion the use of a catheter balloon, the Examiner agrees that the reference does not disclose the intended use of the PTFE tube as "a catheter balloon". Nevertheless, a statement of usefulness or contemplated use of a claimed compound or composition in a claim is usually given little weight in distinguishing over the prior art. In re Maeder et al. (CCPA 1964) 337 F2d 875, 143 USPQ 248; In re Riden et al. (CCPA 1963) 318 F2d 761, 138 USPQ 112; In re Sinex (CCPA 1962) 309 F2d 488, 135 USPQ 302. Further, it is noted that Applicant has amended independent claim 1 by incorporating a functional limitation in which the balloon being collapsible

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to a small size and inflatable to a maximum diameter. This functional limitation of being collapsible to a small size and inflatable to a maximum diameter is an inherent behavioral characteristics of a balloon because one of ordinary skill in the art would anticipate for a balloon to be inflated up to the maximum diameter of its inner wall tube and thereby preventing overinflation and potential rupture of a balloon thereof. Thus, in the absence of evidence to the contrary or specific structural limitations, the claimed PTFE tube disclosed by the reference anticipates claims 1-5 and 8-9 as drafted.

8. The rejection of claims 1-9 under 35 U.S.C. 103(a) as being unpatentable over Buck et al. (U.S. Patent No. 4,925,710) in view of Gore (U.S. Patent No. 3,953,566) and Soltesz (U.S. Patent No. 5,254,107).

The response asserts that the claims are drawn to an inelastic catheter balloon which is flexible and being collapsible to a small size and inflatable to a maximum diameter, absent a disclosure in the prior art of said an inelastic catheter balloon, it is not rendered obvious over the prior art which has been cited, since the combined teachings of the prior art lacks the necessary flexibility for possible use as a catheter balloon is noted. However, it is the Examiner's position for the reasons of record that the functional limitation of being collapsible to a small size and inflatable to a maximum diameter as recited in independent claim 1 is an expected behavioral characteristics of a balloon because one of ordinary skill in the art would expect for a balloon to be inflated up to the maximum diameter of its inner wall tube and thereby preventing overinflation and potential rupture of a balloon thereof.

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With respect to the structure of the balloon to be an inelastic balloon, although, the prior art does not teach the use or construction of balloon *per se*, however, the prior art clearly teach the use or construction of thin-wall tube comprising porous PTFE and a non-porous coating, and as such, it would be conventional and within the ordinary skill in the art to which this invention pertains to expect the tube to be inelastic because the prior art used the same material/composition under substantially the same situation to make the thin-wall catheter tube as the instant claimed thin-wall catheter balloon. Therefore, in the absence of sufficient objective factual evidence or unexpected results to the contrary, it would have been obvious to expect the tube of the prior art to be inelastic tube because of the reasonable expectation of the functional equivalency of the non-porous coating material.

Thus, it is the Examiner's position that in view of the combined teachings of the prior art and in view of the above, one of ordinary skill in the art would have been motivated at the time the invention was made to use or easily adapt the already known system of manufacturing ePTFE described in the combined teachings of the prior art for the intended purpose of obtaining a non-porous catheter balloon comprising porous PTFE provided with a non-porous coating, said balloon being collapsible to a small size and inflatable to a maximum diameter is an obvious modification of the prior art combined teachings at the time the invention was made. Thus, it is made obvious by the combined teachings of the prior art since the instantly claimed invention which falls within the scope of the prior art teachings would have been obvious because as held in host of cases including *Ex parte Harris*, 748 O.G. 586; *In re Rosselete*, 146 USPQ 183; *In re*

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Burgess, 149 USPQ 355 and as exemplified by *In re Betz*, “the test of obviousness is not express suggestion of the claimed invention in any and all of the references but rather what the references taken collectively would suggest to those of ordinary skill in the art presumed to be familiar with them”.

The following is a new ground of rejection necessitated by Applicant’s amendment

NEW GROUND OF REJECTION

CLAIMS REJECTION-35 U.S.C. § 112^{2nd} PARAGRAPH

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 and claims dependent thereto are indefinite as amended because “.....provided with a non-porous coating.....” does not identify where and how the coating is provided since there is no functional recitation as to where and how the non-porous coating is provided.

Amendment of the claim to recite “.....provided with a non-porous coating over the porous PTFE to render the balloon non-porous.....” is suggested. *OK*

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Claim 1 is also indefinite in the recitation “a small size” and “a maximum diameter” because these are relative expressions and as such they are not clear nor ascertainable whether the expressions do provide degree of leeways with respect to ranges. Further, it is unclear if the balloon is collapsible and inflatable to a tube or other material. Appropriate clarification is required.

ACTION IS FINAL, NECESSITATED BY AMENDMENT

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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CONCLUSION AND FUTURE CORRESPONDENCE


11. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abdel A. Mohamed whose telephone number is (703) 308-3966. The examiner can normally be reached on Monday through Friday from 5:30 a.m. to 5:00 p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (703) 308-2923. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

 Mohamed/AAM

December 29, 2000